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Last Name	Given Name and M.I.	Residence (City, State/Foreign Country)
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<input type="checkbox"/> Additional inventors are being named on separately numbered sheets attached hereto.		
TITLE OF INVENTION (280 characters max)		
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CORRESPONDENCE ADDRESS		
Please associate the address of record with the following Customer Number as the Correspondence Address for this application:		
Customer No. 00757 - Brinks Hofer Gilson Lione		
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Respectfully submitted,


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

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TITLE: A FLEXIBLE TIP

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A FLEXIBLE TIP

BACKGROUND

[0001] Catheters are tube-like medical devices that may be inserted into a body cavity, organ, or blood vessel for diagnostic or therapeutic reasons. Catheters may be designed for insertion into the vasculature and are available for a wide variety of purposes, including diagnosis, interventional therapy, drug delivery, drainage, perfusion, and the like. They may also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like. Catheters for each of these and other purposes can be introduced to numerous target sites within a patient's body by guiding the catheter through an incision made in the patient's skin.

[0002] Catheters generally have an elongated, flexible catheter body enclosing one or more lumens. The lumen(s) may extend from the proximal end to the distal end of the catheter body. The diameter of the lumen(s) may vary throughout the length of the catheter, such as when the lumens have a larger diameter at the proximal end than at the distal end, or the diameter of the lumen(s) may be uniform. When an inner body is placed substantially in the center of the outermost body, the lumens may be coaxially arranged. The catheter body may be relatively straight, inherently curved, or curved by insertion of a curved stiffening wire or wire guide through a catheter lumen. The catheter body may assume a straight or linear configuration, when free from external bending forces. The catheter body may be highly flexible and thus capable of passing through the tortuous twists and turns of a patient's vasculature. In some cases, the catheter body may have a shaped distal end portion including curves and bends, which are selected to facilitate introduction and placement of the catheter in the vascular system. A particular geometry of curves and/or

bends may be selected to accommodate the intended use of the catheter. The distal end of the catheter may also be equipped with an inflatable balloon to expand a medical device, such as a stent, and/or to dilate a vessel.

[0003] A lumen, extending through the length of a catheter, is often designed to enable the catheter to be employed in conjunction with a wire guide. This type of catheter is generally referred to as an over-the-wire catheter. There are many different types of over-the-wire catheters, including those adapted for dilation and stent delivery.

[0004] The wire guide is a small wire that is inserted into the patient in advance of an over-the-wire catheter. This wire may be inserted through a patient's skin and then fed along the desired conduit, such as a blood vessel, until it reaches the desired location. The smaller diameter and the malleability of the wire guide generally make it easier to feed through a potentially tortuous conduit, compared to the catheter itself. Once the wire guide has reached the location where treatment is to occur, the distal end of the over-the-wire catheter is fed over the proximal end of the wire guide. Next, the catheter may be advanced over the wire guide, and to the desired location, by applying force to the proximal end of the catheter.

[0005] The distal end of the catheter body may terminate in a catheter tip. There are a wide variety of different catheter tips, including rotating tips, shaped tips, cutting tips, and soft tips. Many of these distal catheter tips are designed to reduce the potential for trauma, such as the abrasion or puncture of the conduit, such as a blood vessel.

[0006] Reducing the potential for trauma to a conduit can involve modifying a variety of catheter tip design features. For example, some catheter tips are rounded and/or soft, which may reduce the risk of

abrasion by allowing the catheter to more easily move through the conduit. Other catheter tips are designed to be more flexible and/or compressible. A flexible tip may be more likely to deflect if forced against a wall of the conduit, rather than puncturing the conduit wall. Similarly a compressible tip may be less likely to puncture the wall of the conduit, since such a tip may reduce the force with which a catheter contacts an obstruction or the conduit wall. Additionally, a flexible and/or compressible catheter tip may allow the catheter to be more easily advanced over a wire guide. This is particularly important when the catheter is being advanced over a wire guide containing one or more sharp curves or turns. If the catheter can be easily advanced over a wire guide it may decrease the risk of abrasion and/or puncture.

BRIEF SUMMARY

[0007] In one aspect of the invention, there is an elongate flexible catheter tip comprising a longitudinal axis extending between a proximal end and a distal end. These aspects may further include a corrugated region located between the proximal end and the distal end.

[0008] In a further aspect of the invention, there is a dilation catheter comprising an elongate outer body comprising a longitudinal axis extending between an outer proximal end and an outer distal end. These aspects may further include an elongate inner body, comprising a proximal region located within the outer body and extending between the outer proximal end and the outer distal end, a distal region extending past the outer distal end and comprising an inner distal end, and an inner lumen contained within the inner body. These aspects may further include an outer lumen defined by the outer body and the inner body, an elongate flexible tip comprising a proximal tip end, a distal tip end, and a corrugated

region located between the proximal tip end and the distal tip end, wherein the proximal tip end is adjacently attached to the inner distal end. These aspects may further include a balloon comprising a proximal balloon leg attached to the outer distal end, a distal balloon leg attached to a distal end of the dilation catheter, and a balloon cavity defined by the proximal balloon leg and the distal balloon leg and in fluid communication with the outer lumen.

[0009] In a further aspect of the invention, there is a dilation catheter comprising an elongate body comprising a longitudinal axis extending between a proximal body end and a distal body end, an inflation lumen and a wire guide lumen, wherein the inflation lumen and the wire guide lumen are parallel and are defined by the elongate body, and an intermediate region positioned between the proximal body end and the distal body end. These aspects may further include an elongate flexible tip comprising a longitudinal axis extending between a proximal tip end and a distal tip end, wherein the proximal tip end is adjacently attached to the distal body end, a corrugated region located between the proximal tip end and the distal tip end, and a tip lumen defined by the elongate flexible tip, wherein the tip lumen is aligned with the wire guide lumen. These aspects may further include a balloon comprising a proximal balloon leg attached to the intermediate region, a distal balloon leg adjacently attached to the distal body end, and a balloon cavity defined by the proximal balloon leg and the distal balloon leg, and in fluid communication with the inflation lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The invention can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

[0011] **Fig. 1** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip.

[0012] **Fig. 2** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible catheter tip, wherein a distal end of the flexible tip includes a rounded end.

[0013] **Fig. 3** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end is adjacently attached to a distal balloon leg and an inner distal end.

[0014] **Fig. 4** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter, wherein the catheter includes an elongate flexible tip.

[0015] **Fig. 5** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein the flexible tip is attached to an inner distal end, forming a tip-end attachment.

[0016] **Fig. 6** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein an elongate inner body is reinforced with a braided coil.

[0017] **Fig. 7** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with a flexible tip, wherein the flexible tip is attached to a distal face.

[0018] **Fig. 8** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein an

elongate inner body is composed of an inner material and an outer material.

[0019] **Fig. 9** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein the flexible tip is attached via an external mounting shoulder.

[0020] **Fig. 10** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end is adjacently attached to a distal balloon leg and a distal body end.

[0021] **Fig. 11** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter, wherein the catheter may include an elongate flexible tip.

[0022] **Fig. 12** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end is adjacently attached to a distal body end, forming a tip-end attachment.

[0023] **Fig. 13** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end may be adjacently attached to a distal body end via a distal face.

[0024] **Fig. 14** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter with an elongate flexible tip, wherein a proximal tip end may be adjacently attached to a distal body end via an external mounting shoulder.

[0025] **Fig. 15** illustrates a cross-sectional view through lines A—A of Figs. 3 to 9.

[0026] **Fig. 16** illustrates a cross-sectional view through lines B—B of Figs. 10 to 14.

DETAILED DESCRIPTION

[0027] Reducing the potential for trauma to a conduit can involve modifying a variety of catheter tip design features. For example, some catheter tips are rounded and/or soft, while others are designed to be more flexible and/or compressible. A flexible tip may be more likely to deflect if forced against a wall of the conduit, while a compressible tip may be less likely to puncture the wall of the conduit. Additionally, a flexible and/or compressible catheter tip may allow the catheter to be more easily advanced over a wire guide. This is particularly important when the catheter is being advanced over a wire guide containing one or more sharp curves or turns. If the catheter can be easily advanced over a wire guide it may further decrease the risk of abrasion and/or puncture. The following examples illustrate an elongate flexible catheter tip and the incorporation of this tip in a variety of catheters.

[0028] **Fig. 1** illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible tip **100**. The flexible tip **100** may have a longitudinal axis extending between a proximal end **110** and a distal end **120**. The flexible tip **100** may be made from any suitable material, including, but not limited to, polyethylene, polyamides, polyethers, polyether-block co-polyamide polymers and combinations thereof. For example, the flexible tip **100** may be made from a polyether-block co-polyamide polymers, which may include a copolymer of amide monomers

copolymerized with polyether monomers. Because the amide monomers may have greater structural "rigidity" in comparison to the polyether monomers, the rigidity of the resulting flexible tip **100** to deformation, such as bending or stretching, may be altered. The flexible tip **100** may also be made from laminates of these materials. One example of a suitable polyether-block co-polyamide polymer from which the flexible tip **100** can be made is PEBA[®], which is available from Elf Atofina, Philadelphia, PA. In one aspect, a blend of PEBA[®] polyether-block co-polyamide polymers may be used. In another configuration, the flexible tip **100** may be made from a polyamide polymer, such as nylon 12.

[0029] In one configuration, the flexible tip **100** may comprise a tube member **130**. The tube member **130** may define a lumen **150**, extending longitudinally from the proximal end **110** to the distal end **120** of the flexible tip **100**. In another configuration, the flexible tip **100** may be solid, such that no lumen is present (not shown). The flexible tip **100** and the corrugated region **160** may both vary in length. For example, the flexible tip **100** may range from about 2 mm to about 2 cm in length. In a preferred configuration, the flexible tip **100** may range from about 3 mm to about 1 cm in length.

[0030] The flexible tip **100** may include a corrugated region **160**, located between the proximal end **110** and the distal end **120**. The corrugated region **160** may be produced by applying a force to the precursor of tube member **130**. For example, the precursor to tube member **130** may be placed over a mandrel and the force may be applied in-line with the precursor of tube member **130**. The application of this type of force may cause the tube member **130** to buckle, producing the corrugated region **160**. In one configuration, the precursor of tube member **130** may be heated, using steam for example, during or after application of

the force. Application of the heat during this process may provide the flexible tip 100 with memory, such that the flexible tip 100 may maintain the corrugated shape of the corrugated region 160 more efficiently.

[0031] The corrugated region 160 may possess several inherent features, including flexibility, deflectability, compressibility and conformability, which may contribute to theatraumatic nature of the flexible tip. For example, when a wire guide is not present, the corrugated region 160 may impart flexibility to the tip 100. This flexibility may allow the tip 100 to preferentially deflect, if forced against an obstruction, such as a blood vessel wall, rather than puncturing the obstruction.

[0032] The corrugated region 160 may also contribute to the compressibility of the flexible tip 100. When the flexible tip 100 contacts an obstruction, the compressibility of the flexible tip 100 may reduce the amount of force transferred to the obstruction by the flexible tip 100. The corrugated region 160 of the flexible tip 100 may also provide a catheter tip which will better conform to the wire guide. This may be especially true if the catheter is being advanced over the wire guide containing sharp curves or bends. This conformability may result from the ability of the flexible tip to transfer torque around a sharp bend, when following the wire guide. The conformability, or the ability to transfer torque around a sharp bend, may allow a physician to more easily advance the corresponding catheter over the wire guide by reducing the amount of force that the physician must apply.

[0033] Fig. 2 illustrates, by means of a longitudinal cross-sectional view, an example of an elongate flexible tip 200, wherein a distal end 205 of the flexible tip 200 includes a rounded end 210. The flexible tip 200 may have a longitudinal axis extending between a proximal end 215 and the distal end 205. The flexible tip 200 may include a corrugated region

220, which may be located between the proximal end **215** and the distal end **205**.

[0034] The rounded end **210** may enhance the deflectability of the flexible tip **200**. In one configuration, the rounded end **210** may be integral with the flexible tip **200**. In another configuration, the rounded end **210** may be a separate piece or component that is attached to the distal end of the flexible tip **200**. The rounded end **210** may be made of a material which is of a lower durometer than the flexible tip **200**, thus providing enhanced softness for the rounded end **210**. The enhanced softness of the rounded end **210** may help to prevent abrasions or snagging on obstructions, as the flexible tip **200** is advanced through a conduit. In addition, it may further improve the deflectability of the flexible tip **200**.

[0035] A catheter having a flexible tip containing a corrugated region may be employed for a variety of applications, including diagnosis, interventional therapy, drug delivery, drainage, perfusion, and the like. Such a catheter may also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like. Furthermore a flexible tip containing a corrugated region may be incorporated into a dilation catheter, wherein a balloon may be attached to the catheter (and/or tip) using a variety of attachment configurations.

[0036] For example, **Fig. 3** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter **300** with an elongate flexible tip **302**, wherein a proximal tip end **303** is adjacently attached to a distal balloon leg **305** and an inner distal end **310**. The dilation catheter **300** may be composed of an elongate outer body **315** and an elongate inner body **320**. The outer body **315** may have a longitudinal axis extending between an outer proximal end **317** and an outer distal end **318**. The outer body

315 and the inner body **320** may define an outer lumen **325** therebetween. The inner body **320** may include a proximal region **327**, located within the outer body **315** and extending between the outer proximal end **317** and the outer distal end **318**. Furthermore, the inner body **320** may have a distal region **328**, extending past the outer distal end **318** and comprising the inner distal end **310**. The inner body **320** may contain a single inner lumen **330**.

[0037] The elongate flexible tip **302** may include the proximal tip end **303**, a distal tip end **335**, and a corrugated region **340** located between the proximal tip end **303** and the distal tip end **335**. The distal tip end **335** may be integral with a rounded distal end **345** or the rounded distal end **345** may be a separate piece or component that is attached to the distal tip end **335**.

[0038] The dilation catheter **300** may be fitted with a balloon **350**. The balloon **350** may have a balloon cavity **355** in fluid communication with the outer lumen **325**, wherein the balloon cavity **355** may be defined by a proximal balloon leg **360** and the distal balloon leg **305**. The proximal balloon leg **360** may be attached to the outer distal end **318**. The proximal tip end **303**, the distal balloon leg **305**, and the inner distal end **310** may be adjacently attached. In one configuration, the proximal tip end **303** may be sandwiched between the distal balloon leg **305** and the inner distal end **310**.

[0039] In a further example, Fig. 4 illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter **400**, wherein the catheter **400** may include an elongate flexible tip **405**. The dilation catheter **400** may have an elongate outer body **410** and an elongate inner body **415**. The outer body **410** may have a longitudinal axis extending between an outer proximal end **420** and an outer distal end **425**.

The outer body **410** and the inner body **415** may define an outer lumen **430** therebetween. The inner body **415** may include a proximal region **435**, located within the outer body **410** and extending between the outer proximal end **420** and the outer distal end **425**. Furthermore, the inner body **415** may have a distal region **440**, extending past the outer distal end **425** and comprising an inner distal end **445**. The inner body **415** may contain a single inner lumen **450**.

[0040] The elongate flexible tip **405** may include a proximal tip end **455**, a distal tip end **460**, and a corrugated region **465** located between the proximal tip end **455** and the distal tip end **460**. In one configuration, the inner distal end **445** may be attached to the proximal tip end **455**, forming a tip-end attachment **470**. Furthermore, the distal tip end **460** may be integral with a rounded distal end **475**. In another configuration, the rounded distal end **475** may be a separate piece or component that is attached to the distal tip end **460**.

[0041] The dilation catheter **400** may be fitted with a balloon **480**, having a proximal balloon leg **482** and a distal balloon leg **483**. The proximal balloon leg **482** may be attached to the outer distal end **425**. The distal balloon leg **483** may be attached adjacent to the tip-end attachment **470**. It is worth noting that an "adjacent attachment", as used throughout this document, includes an operable connection or a functional connection, such that there may be intervening layers between the two pieces, components or members that are being attached. Furthermore, "adjacently attached" and "attached adjacent to", have the same meaning as that defined for an adjacent attachment. The balloon **480** may have a balloon cavity **485** in fluid communication with the outer lumen **430**, wherein the balloon cavity **485** is defined by the distal balloon leg **482** and the proximal balloon leg **483**.

[0042] In another example, **Fig. 5** illustrates, by means of a longitudinal cross-sectional view, an elongate dilation catheter **500** with an elongate flexible tip **505**, wherein the tip **505** is attached to an inner distal end **510**, forming a tip-end attachment **515**. The dilation catheter **500** may be composed of an elongate outer body **520** and an elongate inner body **525**. The outer body **520** may have a longitudinal axis extending between an outer proximal end **527** and an outer distal end **528**. The outer body **520** and the inner body **525** may define an outer lumen **530** therebetween. The inner body **525** may include a proximal region **535**, located within the outer body **520** and extending between the outer proximal end **527** and the outer distal end **528**. Furthermore, the inner body **525** may have a distal region **540**, extending past the outer distal end **528** and comprising the inner distal end **510**. The inner body **525** may contain a single inner lumen **545**.

[0043] The elongate flexible tip **505** may include a proximal tip end **547**, a distal tip end **548**, and a corrugated region **550** located between the proximal tip end **547** and the distal tip end **548**. In one configuration, the inner distal end **510** may be attached adjacent to the proximal tip end **547**, forming the tip-end attachment **515**. Furthermore, the distal tip end **548** may be integral with a rounded distal end **555**. In another configuration, the rounded distal end **555** may be a separate piece or component that is attached to the distal tip end **548**.

[0044] The dilation catheter **500** also may be fitted with a balloon **560**, having a proximal balloon leg **562** and a distal balloon leg **563**. The proximal balloon leg **562** may be attached to the outer distal end **528**, while the distal balloon leg **563** may be attached to the distal region **540**. The balloon **560** may have a balloon cavity **565** in fluid communication with the outer lumen **530**, wherein the balloon cavity **565** may be defined by the distal balloon leg **563** and the proximal balloon leg **562**.

[0045] In an additional example, **Fig. 6** illustrates, by means of a longitudinal cross-sectional view of an elongate dilation catheter **600** with an elongate flexible tip **602**, wherein an elongate inner body **605** is reinforced with a braided coil **607**. The dilation catheter **600** may be composed of an elongate outer body **610** and the elongate inner body **605**. The outer body **610** may have a longitudinal axis extending between an outer proximal end **612** and an outer distal end **613**. The outer body **610** and the inner body **605** may define an outer lumen **615** therebetween. The inner body **605** may include a proximal region **620**, located within the outer body **610** and extending between the outer proximal end **612** and the outer distal end **613**. Furthermore, the inner body **605** may have a distal region **625**, extending past the outer distal end **613** and comprising an inner distal end **630**. The inner body **605** may contain a single inner lumen **635**.

[0046] The braided coil **607** may serve to reinforce the inner body **605**. The braided coil **607** may be imbedded in the inner body **605**. In another configuration, the braided coil **607** may be adhered to the exterior or the interior of the inner body **605**. The braided coil **607** may extend throughout the entirety of the inner body **605** or the braided coil **607** may only extend through a portion of the inner body **605**. The tightness of the braided coil **607** may affect its flexibility and thus the flexibility of the inner body **605**. If the tightness of the braided coil **607** is decreased, the flexibility of the braided coil **607**, and the corresponding inner body **625**, may be increased. The tightness of the braided coil **607** may be uniform throughout its length or it may vary throughout its length. The flexibility of the inner body **605** may vary throughout the length of the inner body **605**. This may be accomplished by gradually decreasing the tightness of the braided coil **607** throughout the length of the inner body **605**. In one configuration, the braided coil **607** may be constructed from a variety of materials. For example, materials may include stainless steel and nitinol.

[0047] The elongate flexible tip **602** may include a proximal tip end **640**, a distal tip end **645**, and a corrugated region **650** located between the proximal tip end **640** and the distal tip end **645**. In one configuration, the proximal tip end **640** may be attached adjacent to the inner distal end **630** (not shown). In another configuration, the proximal tip end **640** may be integral with the inner distal end **630**. Furthermore, the distal tip end **645** may be integral with a rounded distal end **651** or the rounded distal end **651** may be a separate piece or component that is attached to the distal tip end **645**.

[0048] The dilation catheter **600** may be fitted with a balloon **655**, having a proximal balloon leg **660** and a distal balloon leg **661**. The proximal balloon leg **660** may be attached to the outer distal end **613**. The distal balloon leg **661** may be attached to inner distal end **630**. The balloon **655** may have a balloon cavity **665** in fluid communication with the outer lumen **615**, wherein the balloon cavity **665** is defined by the proximal balloon leg **660** and the distal balloon leg **661**.

[0049] In another example, Fig. 7 illustrates a longitudinal cross-sectional view of an elongate dilation catheter **700** with a flexible tip **705**, wherein the tip may be attached to a distal face **707**. The dilation catheter **700** may be composed of an elongate outer body **710** and an elongate inner body **715**. The outer body **710** may have a longitudinal axis extending between an outer proximal end **716** and an outer distal end **717**. The outer body **710** and the inner body **715** may define an outer lumen **720** therebetween. The inner body **715** may include a proximal region **725**, located within the outer body **710** and extending between the outer proximal end **716** and the outer distal end **717**. Furthermore, the inner body **715** may have a distal region **730**, extending past the outer distal end **717** and comprising an inner distal end **735**. The inner body **715** may contain a single inner lumen **740**.

[0050] The dilation catheter 700 also may be fitted with a balloon 745 having a proximal balloon leg 750 and a distal balloon leg 755. The proximal balloon leg 750 may be attached to the outer distal end 717. The distal balloon leg 755 may be attached to the inner distal end 735, forming a distal bonding region 760. The distal bonding region 760 may form the distal face 707. In one configuration, the distal face 707 may form an angular groove, circumscribing the inner lumen 740. In another configuration, the distal face 707 may be a flat surface, perpendicular to the longitudinal axis of the dilation catheter 700 (not shown). The balloon 745 may have a balloon cavity 770 in fluid communication with the outer lumen 720, wherein the balloon cavity 770 is defined by the distal balloon leg 755 and the proximal balloon leg 750.

[0051] The elongate flexible tip 705 may include a proximal tip end 772, a distal tip end 773, and a corrugated region 775 located between the proximal tip end 772 and the distal tip end 773. In one configuration, the proximal tip end 772 may be attached adjacent to distal face 707. Furthermore, the distal tip end 773 may be integral with a rounded distal end 780 or the rounded distal end 780 may be a separate piece or component that is attached to the distal tip end 773.

[0052] In an additional example, **Fig. 8** illustrates a longitudinal cross-sectional view of an elongate dilation catheter 800 with an elongate flexible tip 802, wherein an elongate inner body 805 is composed of an inner material 806 and an outer material 807. The dilation catheter 800 may be composed of an elongate outer body 810 and the elongate inner body 805. The outer body 810 may have a longitudinal axis extending between an outer proximal end 812 and an outer distal end 813. The outer body 810 and the inner body 805 may define an outer lumen 815 therebetween. The inner body 805 may include a proximal region 820, located within the outer

body **810** and extending between the outer proximal end **812** and the outer distal end **813**. Furthermore, the inner body **805** may have a distal region **825**, extending past the outer distal end **813** and comprising an inner distal end **830**. In addition, the outer material **807** may be of a lower durometer than the inner material **806**. The inner body **805** may define a single inner lumen **835**.

[0053] The elongate flexible tip **802** may include a proximal tip end **840**, a distal tip end **845**, and a corrugated region **850** located between the proximal tip end **840** and the distal tip end **845**. The flexible tip **802** may be formed from the outer material **807** of the inner body **805**. In one configuration, the distal tip end **845** may be integral with a rounded distal end **855** or the rounded distal end **855** may be a separate piece or component that is attached to the distal tip end **845**.

[0054] The dilation catheter **800** may be fitted with a balloon **860**, having a proximal balloon leg **862** and a distal balloon leg **863**. The proximal balloon leg **862** may be attached to the outer distal end **813**. The distal balloon leg **863** may be attached to the inner distal end **830**. In another configuration, the distal balloon leg **863** may be attached to the flexible tip **802** (not shown). The balloon **860** may have a balloon cavity **865** in fluid communication with the outer lumen **815**, wherein the balloon cavity **865** is defined by the proximal balloon leg **862** and the distal balloon leg **863**.

[0055] In another example, Fig. 9 illustrates a longitudinal cross-sectional view of an elongate dilation catheter **900** with an elongate flexible tip **905**, wherein the flexible tip **905** may be attached via an external mounting shoulder **907**. The dilation catheter **900** may be composed of an elongate outer body **910** and an elongate inner body **915**. The outer body **910** may have a longitudinal axis extending between an outer proximal end

917 and an outer distal end **918**. The outer body **910** and the inner body **915** may define an outer lumen **920** therebetween. The inner body **915** may include a proximal region **922**, located within the outer body **910** and extending between the outer proximal end **917** and the outer distal end **918**. Furthermore, the inner body **915** may have a distal region **923**, extending past the outer distal end **918** and comprising an inner distal end **925**. The inner body **915** may contain a single inner lumen **930**.

[0056] The dilation catheter **900** may be fitted with a balloon **935**, having a proximal balloon leg **937** and a distal balloon leg **938**. The proximal balloon leg **937** may be attached to the outer distal end **918**. The distal balloon leg **938** may be attached to the distal region **923**, forming the external mounting shoulder **907**. The balloon **935** may have a balloon cavity **940** in fluid communication with the outer lumen **920**, wherein the balloon cavity **940** is defined by the proximal balloon leg **937** and the distal balloon leg **938**.

[0057] The elongate flexible tip **905** may include a proximal tip end **945**, a distal tip end **950**, and a corrugated region **955** located between the proximal tip end **945** and the distal tip end **950**. The proximal tip end **945** may be attached to the external mounting shoulder **907**. Furthermore, the distal tip end **950** may be integral with a rounded distal end **956** or the rounded distal end **955** may be a separate piece or component that is attached to the distal tip end **950**.

[0058] In a further example, Fig. 10 illustrates a longitudinal cross-sectional view of an elongate dilation catheter **1000** with an elongate flexible tip **1002**, wherein a proximal tip end **1003** is adjacently attached to a distal balloon leg **1005** and a distal body end **1010**. The dilation catheter **1000** may be composed of an elongate body **1015**. The elongate body **1015** may have a longitudinal axis extending between a proximal body end

1017 and a distal body end **1010**. In addition, the elongate body **1015** may define parallel dual lumens, an inflation lumen **1025** and a wire guide lumen **1030**, wherein the lumens **1025** and **1030** extend longitudinally through the elongate body **1015**. The wire guide lumen **1030** extends through the distal body end **1010**, whereas the inflation lumen **1025** extends to an intermediate region **1018**. The intermediate region **1018** may be positioned between the proximal body end **1017** and the distal body end **1010**.

[0059] The elongate flexible tip **1002** may comprise a longitudinal axis extending between the proximal tip end **1003** and a distal tip end **1035**. A corrugated region **1040** may be located between the proximal tip end **1003** and the distal tip end **1035**. The distal tip end **1035** may be integral with a rounded distal end **1045** or the rounded distal end **1045** may be a separate piece or component that is attached to the distal tip end **1035**. Additionally, the elongate flexible tip **1002** may comprise a tip lumen **1050** extending from the proximal tip end **1003** through the rounded distal end **1045**, wherein the tip lumen **1050** is aligned with the wire guide lumen **1030**.

[0060] The dilation catheter **1000** may be fitted with a balloon **1055**. The balloon **1055** may have a balloon cavity **1057** in fluid communication with the inflation lumen **1025**, wherein the balloon cavity **1057** may be defined by a proximal balloon leg **1060** and the distal balloon leg **1005**. The proximal balloon leg **1060** may be attached to the intermediate region **1018**. The distal balloon leg **1005** may be adjacently attached to the distal body end **1010** and the proximal tip end **1003**. In one configuration, the proximal tip end **1003** may be sandwiched between the distal balloon leg **1005** and the distal body end **1010**.

[0061] In a further example, Fig. 11 illustrates a longitudinal cross-sectional view of an elongate dilation catheter **1100**, wherein the catheter

1100 may include an elongate flexible tip **1105**. The dilation catheter **1100** may be composed of an elongate body **1120**. The elongate body **1120** may have a longitudinal axis extending between a proximal body end **1122**, and a distal body end **1125**. In addition, the elongate body **1120** may define parallel dual lumens, a wire guide lumen **1130** and an inflation lumen **1135**, wherein the lumens **1130** and **1135** extend longitudinally through the elongate body **1120**. The wire guide lumen **1130** extends through the distal body end **1125**, whereas the inflation lumen **1135** extends to an intermediate region **1123**. The intermediate region **1123** may be positioned between the proximal body end **1122** and the distal body end **1125**.

[0062] The elongate flexible tip **1105** may comprise a longitudinal axis extending between a proximal tip end **1155** and a distal tip end **1160**. A corrugated region **1165** may be located between the proximal tip end **1155** and the distal tip end **1160**. In one configuration, the proximal tip end **1155** is adjacently attached to the distal body end **1125**, forming a tip-end attachment **1170**. The distal tip end **1160** may be integral with a rounded distal end **1175** or may be a separate piece or component that is attached to the distal tip end **1160**. Additionally, the elongate flexible tip **1105** may comprise a tip lumen **1180** extending from the proximal tip end **1155** through the rounded distal end **1175**, wherein the tip lumen **1180** is aligned with the wire guide lumen **1130**.

[0063] The dilation catheter **1100** may be fitted with a balloon **1180**, having a proximal balloon leg **1182** and a distal balloon leg **1183**. The proximal balloon leg **1182** may be attached to the intermediate region **1123**. The distal balloon leg **1183** may be adjacently attached to the distal body end **1125**, the proximal tip end **1155**, and the tip-end attachment **1170**. The balloon **1180** may have a balloon cavity **1185** in fluid communication with the inflation lumen **1135**, wherein the balloon cavity

1185 is defined by the distal balloon leg **1182** and the proximal balloon leg **1183**.

[0064] In another example, **Fig. 12** illustrates a longitudinal cross-sectional view of an elongate dilation catheter **1200** with an elongate flexible tip **1205**, wherein a proximal tip end **1247** is adjacently attached to a distal body end **1210**, forming a tip-end attachment **1215**. The dilation catheter **1200** may be composed of an elongate body **1220**. The elongate body **1220** may have a longitudinal axis extending between a proximal body end **1225**, and the distal body end **1210**. In addition, the elongate body **1210** may define parallel dual lumens, a wire guide lumen **1230** and an inflation lumen **1235**, wherein the lumens **1230** and **1235** extend longitudinally through the elongate body **1220**. The wire guide lumen **1230** extends through the distal body end **1210**, whereas the inflation lumen **1235** extends to an intermediate region **1227**. The intermediate region **1227** may be positioned between the proximal body end **1225** and the distal body end **1210**.

[0065] The elongate flexible tip **1205** may comprise a longitudinal axis extending between the proximal tip end **1247** and a distal tip end **1248**. A corrugated region **1250** may be located between the proximal tip end **1247** and the distal tip end **1248**. The distal body end **1210** may be adjacently attached to the proximal tip end **1247**, forming the tip-end attachment **1215**. In one configuration, the distal tip end **1248** may be integral with a rounded distal end **1255** or the rounded distal end **1255** may be a separate piece or component that is attached to the distal tip end **1248**. Additionally, the elongate flexible tip **1205** may comprise a tip lumen **1260** extending from the proximal tip end **1247** through the rounded distal end **1255**, wherein the tip lumen **1260** is aligned with the wire guide lumen **1230**.

[0066] The dilation catheter **1200** also may be fitted with a balloon **1265**, having a proximal balloon leg **1267** and a distal balloon leg **1268**. The proximal balloon leg **1267** may be attached to the intermediate region **1227**, while the distal balloon leg **1268** may be adjacently attached to the distal body end **1210**. The balloon **1265** may have a balloon cavity **1270** in fluid communication with the inflation lumen **1235**, wherein the balloon cavity **1270** may be defined by the distal balloon leg **1268** and the proximal balloon leg **1267**.

[0067] In another example, Fig. 13 illustrates a longitudinal cross-sectional view of an elongate dilation catheter **1300** with an elongate flexible tip **1305**, wherein a proximal tip end **1372** may be adjacently attached to a distal body end **1325** via a distal face **1307**. The dilation catheter **1300** may be composed of an elongate body **1320**. The elongate body **1320** may have a longitudinal axis extending between a proximal body end **1322**, and the distal body end **1325**. In addition, the elongate body **1320** may define parallel dual lumens, a wire guide lumen **1330** and an inflation lumen **1335**, wherein the lumens **1330** and **1335** extend longitudinally through the elongate body **1320**. The wire guide lumen **1330** extends through the distal body end **1325**, whereas the inflation lumen **1335** extends to an intermediate region **1323**. The intermediate region **1323** may be positioned between the proximal body end **1322** and the distal body end **1325**.

[0068] The dilation catheter **1300** also may be fitted with a balloon **1345** having a proximal balloon leg **1350** and a distal balloon leg **1355**. The proximal balloon leg **1350** may be attached to the intermediate region **1323**. The distal balloon leg **1355** may be adjacently attached to the distal body end **1325**, forming a distal bonding region **1360**, wherein the distal bonding region **1360** may form the distal face **1307**. In one configuration, the distal face **1307** may comprise an angular groove, circumscribing the

wire guide lumen 1330. In another configuration, the distal face 1307 comprises a flat surface, circumscribing the wire guide lumen 1330 (not shown). The balloon 1345 may have a balloon cavity 1370 in fluid communication with the inflation lumen 1335, wherein the balloon cavity 1370 is defined by the distal balloon leg 1355 and the proximal balloon leg 1350.

[0069] The elongate flexible tip 1305 may comprise a longitudinal axis extending between the proximal tip end 1372 and a distal tip end 1373. A corrugated region 1375 may be located between the proximal tip end 1372 and the distal tip end 1373. The distal tip end 1373 may be integral with a rounded distal end 1380 or the rounded distal end 1380 may be a separate piece or component that is attached to the distal tip end 1373. The proximal tip end 1372 may be adjacently attached to the distal body end 1325 via the distal face 1307. Additionally, the elongate flexible tip 1305 may comprise a tip lumen 1377 extending from the proximal tip end 1372 through the rounded distal end 1380, wherein the tip lumen 1377 is aligned with the wire guide lumen 1330.

[0070] In another example, Fig. 14 illustrates a longitudinal cross-sectional view of an elongate dilation catheter 1400 with an elongate flexible tip 1405, wherein a proximal tip end 1445 may be adjacently attached to a distal body end 1415 via an external mounting shoulder 1407. The dilation catheter 1400 may be composed of an elongate body 1410. The elongate body 1410 may have a longitudinal axis extending between a proximal body end 1412, and the distal body end 1415. In addition, the elongate body 1410 may define parallel dual lumens, an inflation lumen 1420 and a wire guide lumen 1425, wherein the lumens 1420 and 1425 extend longitudinally through the elongate body 1410. The wire guide lumen 1425 extends through the distal body end 1415, whereas the inflation lumen 1420 extends to an intermediate region 1413. The

intermediate region **1413** may be positioned between the proximal body end **1412** and the distal body end **1415**.

[0071] The dilation catheter **1400** may be fitted with a balloon **1435**, having a proximal balloon leg **1437** and a distal balloon leg **1438**. The proximal balloon leg **1437** may be attached to the intermediate region **1413**. The distal balloon leg **1438** may be adjacently attached to the distal body end **1415**, forming the external mounting shoulder **1407**. The balloon **1435** may have a balloon cavity **1440** in fluid communication with the inflation lumen **1420**, wherein the balloon cavity **1440** is defined by the proximal balloon leg **1437** and the distal balloon leg **1438**.

[0072] The elongate flexible tip **1405** may comprise a longitudinal axis extending between the proximal tip end **1445** and a distal tip end **1450**. A corrugated region **1455** may be located between the proximal tip end **1445** and the distal tip end **1450**. The proximal tip end **1445** may be adjacently attached to the distal body end **1415** and the distal balloon leg via the external mounting shoulder **1407**. Furthermore, the distal tip end **1450** may be integral with a rounded distal end **1456** or the rounded distal end **1456** may be a separate piece or component that is attached to the distal tip end **1450**. Additionally, the elongate flexible tip **1405** may comprise a tip lumen **1457** extending from the proximal tip end **1445** through the rounded distal end **1456**, wherein the tip lumen **1457** is aligned with the wire guide lumen **1425**.

[0073] Fig. 15 illustrates a cross-sectional view through lines A—A of Figures 3 thru 9. The dilation catheters of Figures 3 thru 9 may comprise an elongate outer body **1505** and an elongate inner body **1510**. The outer body **1505** and the inner body **1510** may define an outer lumen **1515** therebetween. The inner body **1510** may contain a single inner lumen **1520**.

[0074] **Fig. 16** illustrates a cross-sectional view through lines B—B of **Figures 10 thru 14**. The dilation catheters of **Figures 10 thru 14** may comprise an elongate outer body **1605**, wherein the elongate body **1605** may contain parallel dual lumens, an inflation lumen **1610** and a wire guide lumen **1615**.

[0075] It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention.

CLAIMS

1. An elongate flexible catheter tip comprising:
 - a longitudinal axis extending between a proximal end and a distal end; and
 - a corrugated region located between the proximal end and the distal end.
2. The elongate flexible tip of claim 1, wherein the elongate flexible tip comprises a tube member that defines a lumen.
3. The elongate flexible tip of claim 1, further comprising a lumen extending longitudinally throughout the elongate flexible tip body.
4. The elongate flexible tip of claim 1, further comprising a rounded distal end.
5. The elongate flexible tip of claim 3, wherein the elongate flexible tip comprises a material selected from the group consisting of nylon, polyether co-block polyamide polymers, polyethylene, and combinations thereof.
6. A dilation catheter comprising:
 - an elongate outer body comprising a longitudinal axis extending between an outer proximal end and an outer distal end;
 - an elongate inner body, comprising:
 - a proximal region located within the outer body and extending between the outer proximal end and the outer distal end,
 - a distal region extending past the outer distal end and comprising an inner distal end, and
 - an inner lumen contained within the inner body;
 - an outer lumen defined by the outer body and the inner body;
 - an elongate flexible tip comprising a proximal tip end, a distal tip end and a corrugated region located between the proximal tip end and the distal tip end, wherein the proximal tip end is adjacently attached to the inner distal end; and
 - a balloon comprising:

- a proximal balloon leg attached to the outer distal end;
a distal balloon leg attached to a distal end of the
dilation catheter; and
a balloon cavity defined by the proximal balloon leg and
the distal balloon leg and in fluid communication with the outer
lumen.
7. The dilation catheter of claim 6, wherein the elongate flexible tip
comprises a material selected from the group consisting of nylon,
polyether-block co-polyamide polymers, polyethylene, and combinations
thereof.
8. The dilation catheter of claim 6, wherein:
- the proximal tip end is attached to the inner distal end at a tip-
end attachment;
- the distal balloon leg is attached across the tip-end
attachment; and
- the distal tip end comprises a rounded distal end.
9. The dilation catheter of claim 6, wherein:
- the proximal tip end is attached to the inner distal end at a tip-
end attachment;
- the distal balloon leg is attached to the distal region, proximal
to the tip-end attachment; and
- the distal tip end comprises a rounded distal end.
10. The dilation catheter of claim 6, wherein:
- the elongate inner body comprises a braided coil reinforcing
the elongate inner body;
- the inner distal end is integral with the elongate flexible tip;
- the distal balloon leg is attached to the distal region, proximal
to the corrugated region; and
- the distal tip end comprises a rounded distal end.
11. The dilation catheter of claim 10, wherein:

- the braided coil is of uniform tightness, throughout the elongate inner body.
12. The dilation catheter of claim 10, wherein:
- the braided coil is of varying tightness throughout the elongate inner body.
13. The dilation catheter of claim 6, wherein:
- the distal balloon leg is attached to the inner distal end, providing a distal bonding region, wherein the distal bonding region has a distal face circumscribing the inner distal end;
- the proximal tip end is attached to the distal face; and
- the distal tip end comprises a rounded distal end.
14. The dilation catheter of claim 6, wherein:
- the distal balloon leg is attached to the distal region;
- the elongate inner body comprises an inner material and an outer material, wherein:
- the outer material has a lower durometer than the inner material;
- the outer material extends distally beyond the inner material and is integral with the tip;
- the distal tip end comprises a rounded distal end.
15. The dilation catheter of claim 6, wherein:
- the distal balloon leg is attached to the distal region, such that the distal region extends beyond the balloon leg, comprising an external mounting shoulder;
- the flexible tip is attached to the external mounting shoulder; and
- the distal tip end comprises a rounded distal end.
16. The dilation catheter of claim 6, wherein:
- the distal balloon leg is attached adjacent to the inner distal end and the proximal end of the flexible tip.
17. A dilation catheter comprising:

an elongate body comprising:

a longitudinal axis extending between a proximal body end and a distal body end;

an inflation lumen and a wire guide lumen, wherein the inflation lumen and the wire guide lumen are parallel and are defined by the elongate body;

an intermediate region positioned between the proximal body end and the distal body end;

an elongate flexible tip comprising:

a longitudinal axis extending between a proximal tip end and a distal tip end, wherein the proximal tip end is adjacently attached to the distal body end;

a corrugated region located between the proximal tip end and the distal tip end; and

a tip lumen defined by the elongate flexible tip, wherein the tip lumen is aligned with the wire guide lumen;

a balloon comprising:

a proximal balloon leg attached to the intermediate region;

a distal balloon leg adjacently attached to the distal body end; and

a balloon cavity defined by the proximal balloon leg and the distal balloon leg, and in fluid communication with the inflation lumen.

18. The dilation catheter of claim 17, wherein the elongate flexible tip comprises a material selected from the group consisting of nylon, polyether-block co-polyamide polymers, polyethylene, and combinations thereof.

19. The dilation catheter of claim 17, wherein:

the proximal tip end is adjacently attached to the distal body end forming a tip-end attachment;

- the distal balloon leg is adjacently attached to the distal body end, the proximal tip end, and the tip-end attachment; and
 - the distal tip end is integral with a rounded distal end.
- 20. The dilation catheter of claim 17, wherein:
 - the proximal tip end is adjacently attached to the distal body end forming a tip-end attachment;
 - the distal balloon leg is adjacently attached to the distal body end; and
 - the distal tip end is integral with a rounded distal end.
- 21. The dilation catheter of claim 17, wherein:
 - the distal balloon leg is adjacently attached to the distal body end, forming a distal bonding region, wherein the distal bonding region has a distal face that circumscribes the wire guide lumen;
 - the proximal tip end is adjacently attached to the distal body end and the distal balloon leg via the distal face; and
 - the distal tip end is integral with a rounded distal end.
- 22. The dilation catheter of claim 17, wherein:
 - the distal balloon leg is adjacently attached to the distal body end, forming an external mounting shoulder;
 - the proximal tip end is adjacently attached to distal body end and the distal balloon leg via the external mounting shoulder; and
 - the distal tip end comprises a rounded distal end.
- 23. The dilation catheter of claim 17, wherein:
 - the distal balloon leg is adjacently attached to the distal body end and the proximal tip end.

ABSTRACT OF THE DISCLOSURE

An elongate flexible catheter tip is disclosed herein. This catheter tip may include a longitudinal axis extending between a proximal end and a distal end. It may further comprise a corrugated region located between the proximal end and the distal end. The elongate flexible catheter tip, as disclosed herein, may be employed with a large variety of dilation catheters.

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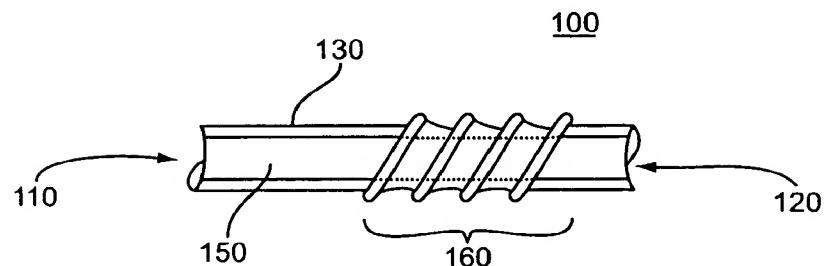


FIG. 1

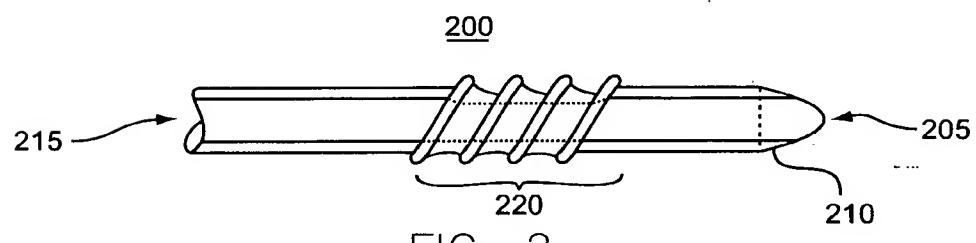


FIG. 2

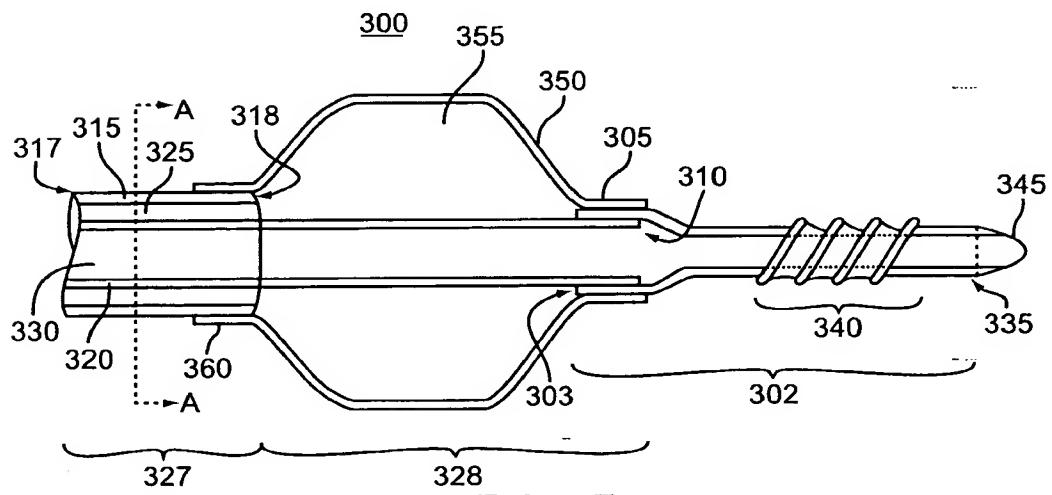


FIG. 3

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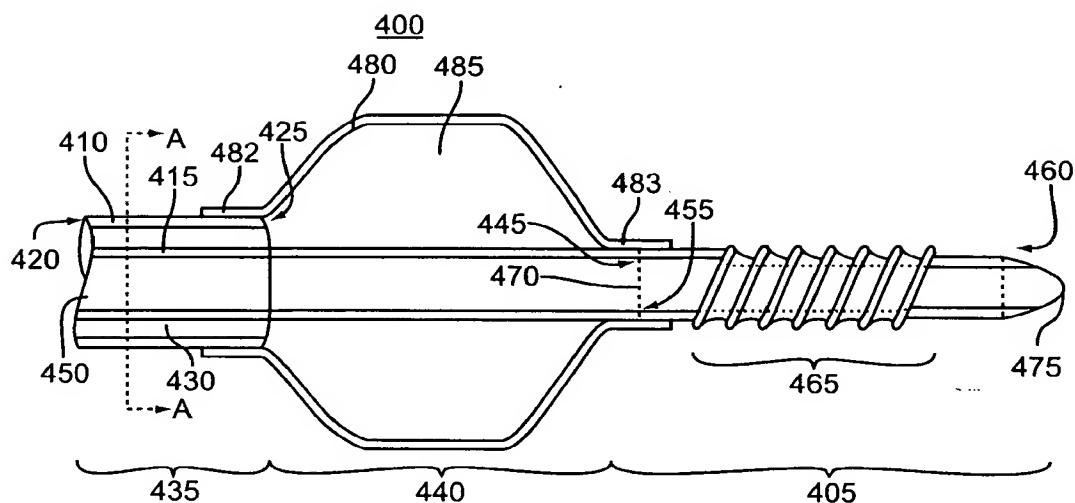


FIG. 4

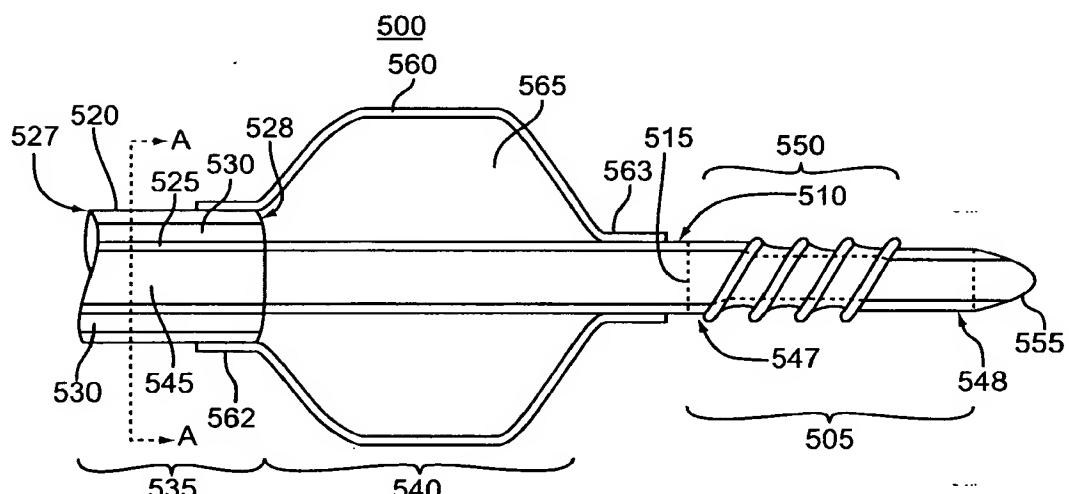
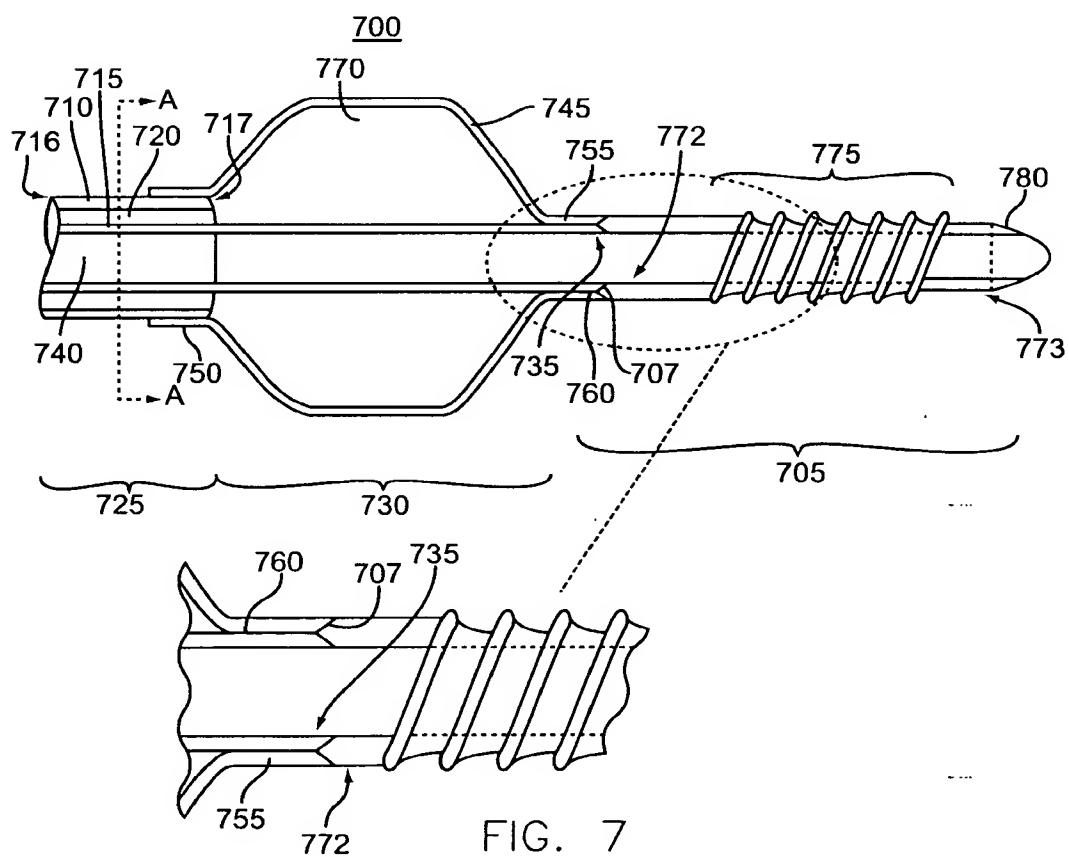
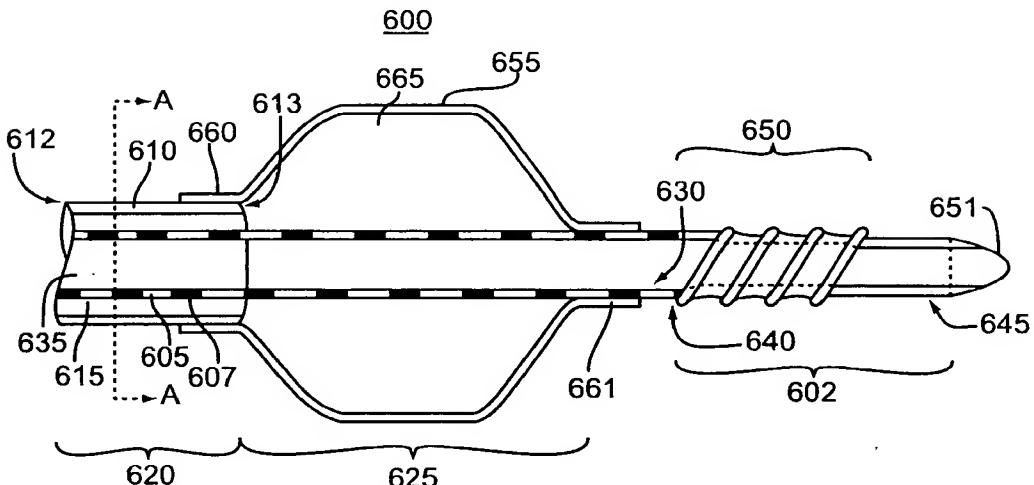
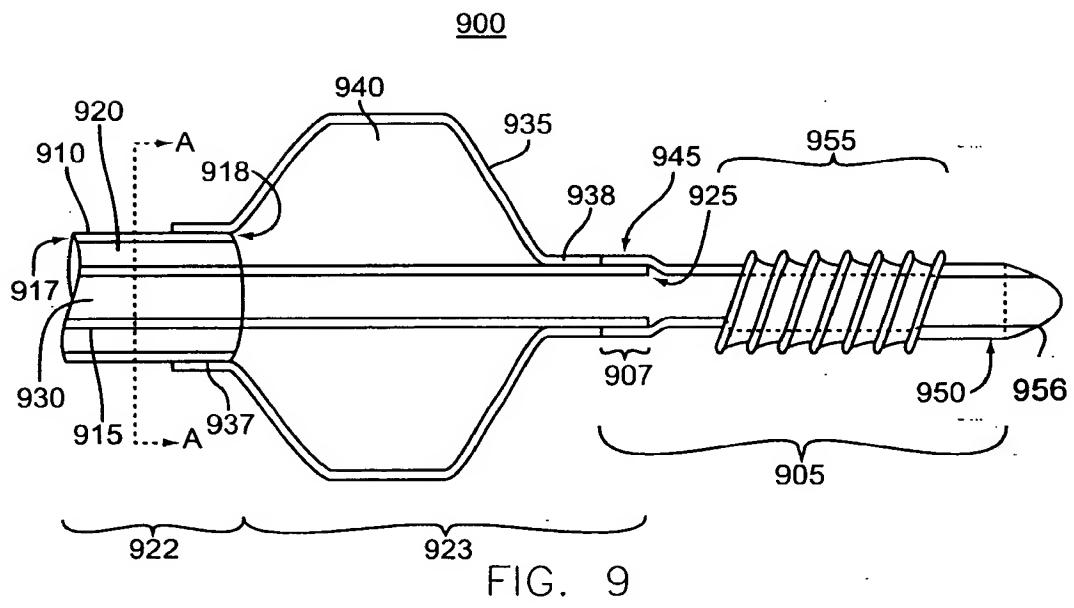
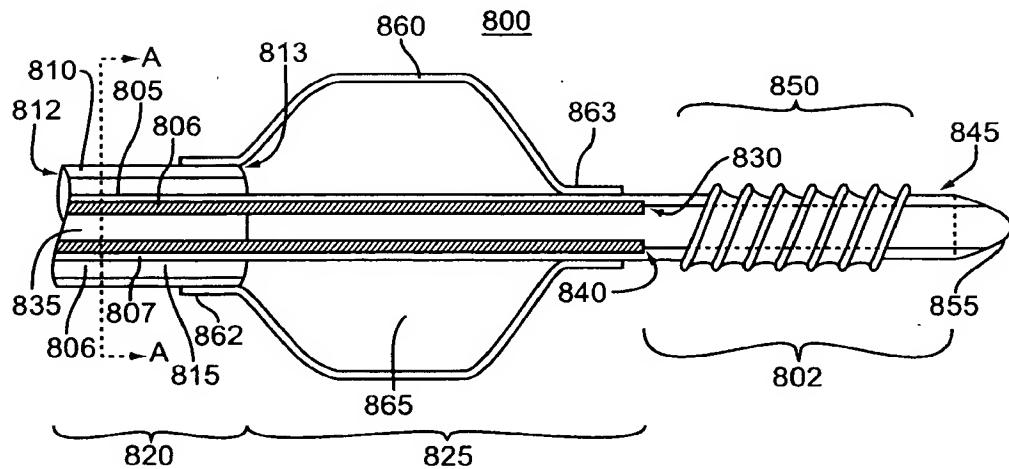


FIG. 5

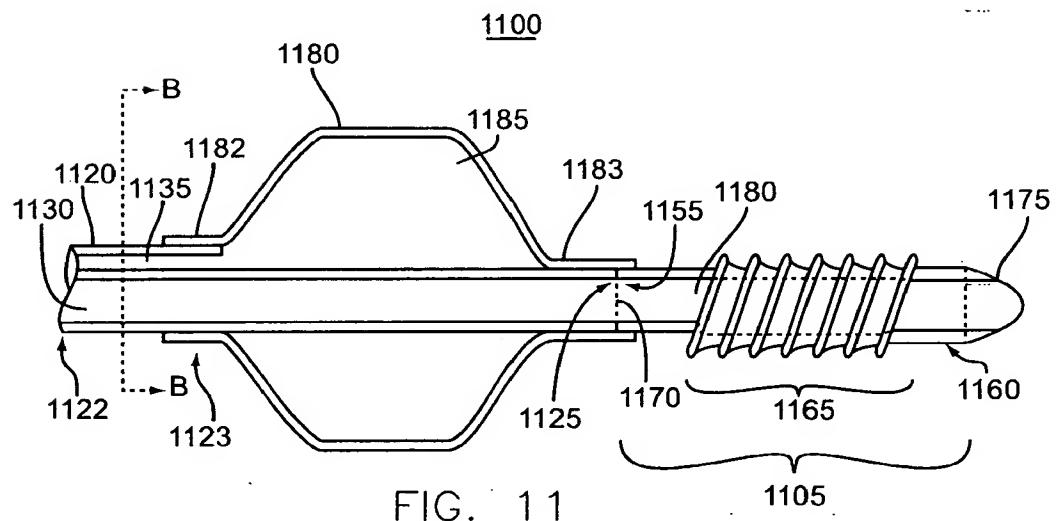
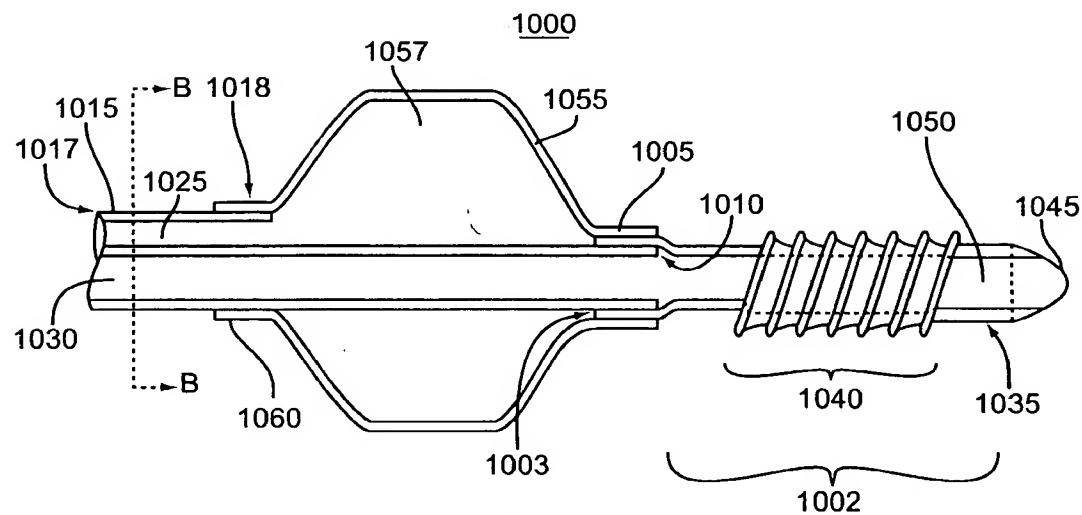
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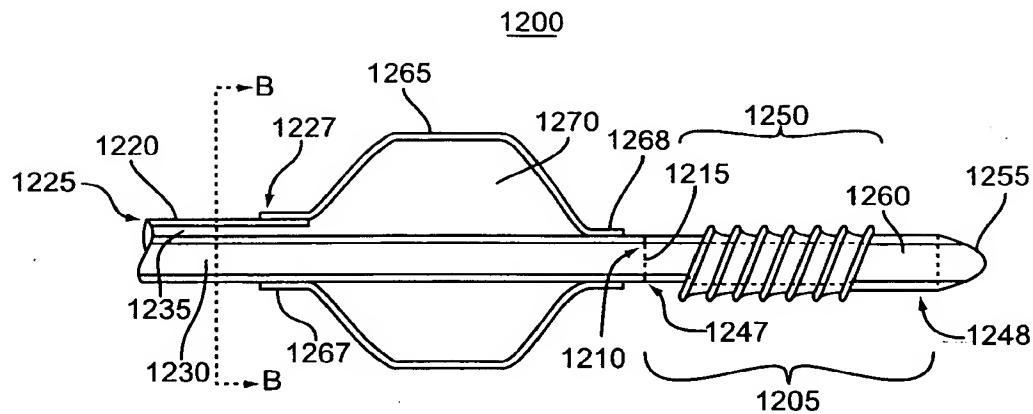


FIG. 12

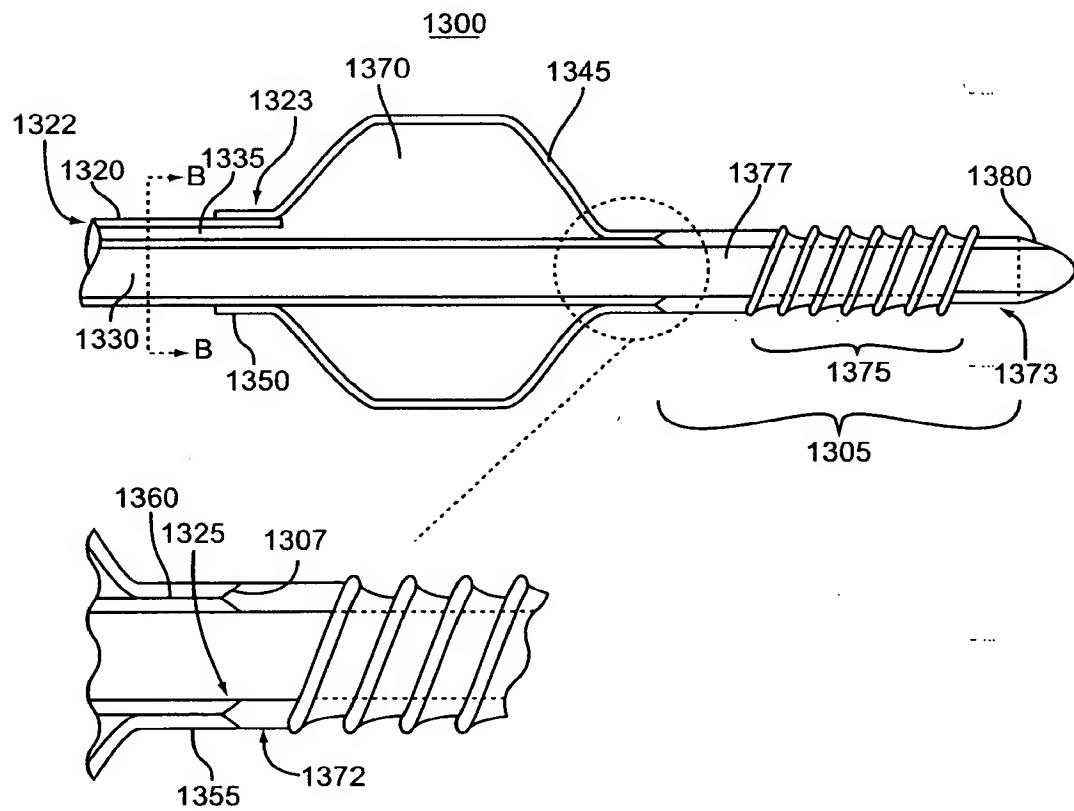


FIG. 13

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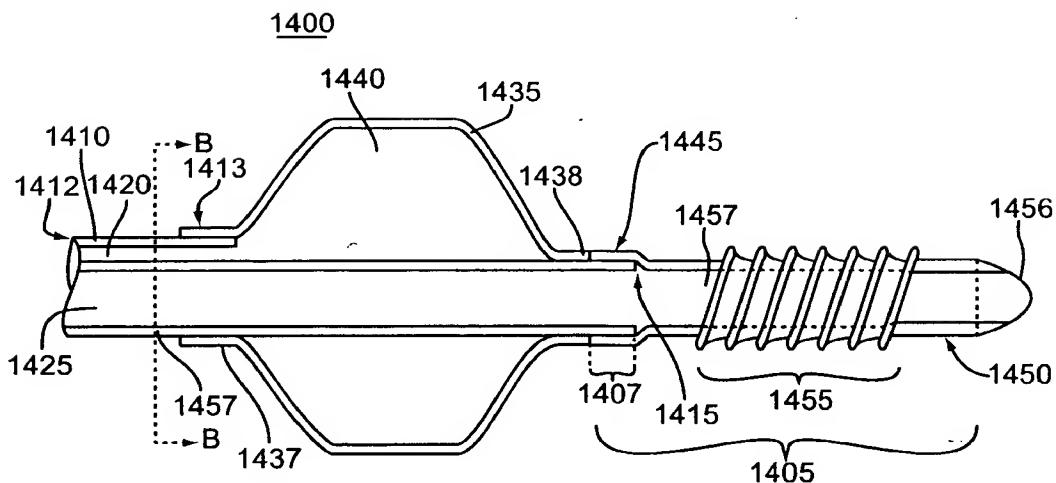


FIG. 14

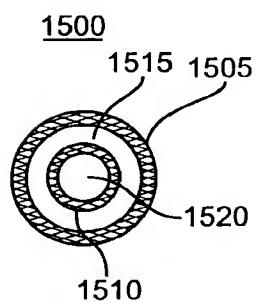


FIG. 15

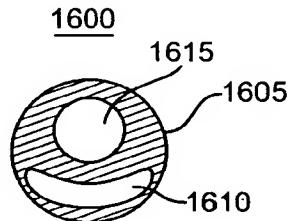


FIG. 16